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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/934,634	08/23/2001	Reginald M. Gorczynski	9579-34	8735

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EXAMINER

ROARK, JESSICA H

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 08/08/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/934,634

Applicant(s)

GORCZYNSKI ET AL.

Examiner

Jessica H. Roark

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 May 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 6-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

1. Claims 1-18 are pending.

2. Applicant's election with traverse of Group I (claims 1-5) in Paper No. 9 is acknowledged. The traversal is on the ground that the invention of Group V is classified in the same Class and subclass as the invention of Group I and so no additional search would be required to search both groups. This is not found persuasive because although there is some overlap in the search of Groups I and V, the searches are not co-extensive.

The requirement is still deemed proper and is therefore made FINAL.

Claims 6-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

*Claims 1-5, as they read on the method with respect to the OX-2 protein or fragment thereof, are under consideration in the instant application.*

3. In order to facilitate the prosecution of this application, *Applicant is requested to cancel all non-elected embodiments from the claims, e.g., the nucleic acid sequence in claim 1.*

### Drawings

4. The formal drawings submitted 12/3/01 are acknowledged.

### IDS

5. Applicant's IDS, filed 1/24/02 (Paper No. 7), is acknowledged.

6. The references cited at the end of the specification have been considered only with respect to the information disclosed in the title, unless cited on a PTO 892. The references *will not* be listed on any patent resulting from this application because they were not provided on a separate list in compliance with 37 CFR 1.98(a)(1). In order to have the references printed on such resulting patent, a separate listing, preferably on a PTO-1449 form, must be filed within the set period for reply to this Office action.

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***Specification***

7. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed*.

It is suggested that Applicant amend the title to include reference to the OX-2 protein.

8. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

9. The status of nonprovisional parent application 09/570,367 should be updated in the first line of the specification to indicate that it is now U.S. Pat. No. 6,338,851.

***Claim Rejections - 35 USC § 112 first paragraph***

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

11. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of preventing, inhibiting or reducing fetal loss comprising administering an effective amount of an OX-2 protein or a fragment of an OX-2 protein which is an extracellular domain of the OX-2 protein of a fragment which possess one or more testable functional properties of the full length OX-2 protein, such as inhibition of a mixed leucocyte reaction (MLR) as disclosed on page 8; does not reasonably provide enablement for a method preventing, inhibiting or reducing fetal loss comprising administering an effective amount of *any* "fragment" of an OX-2 protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification does not provide a sufficient enabling description of the claimed invention. A person of skill in the art is not enabled to use *any* "fragment" of an OX-2 protein as currently recited.

The specification discloses that a fragment comprising the extracellular domain of OX-2 fused to an immunoglobulin constant domain has functional properties consistent with the general ability to suppress an immune response, for example, the functional activity of inhibiting an MLR, as disclosed in the specification as-filed on page 69, Example 6b, for a mouse OX-2:Fc soluble fusion protein. This same OX-2:Fc soluble fusion protein is disclosed on page 73 and in Figure 20 to reduce the resorption rate in a mouse model of spontaneous abortion.

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However, there is insufficient guidance in the specification as-filed to direct a person of skill in the art in how to use *any* "fragment" of an OX-2 protein, other than a "fragment" of an OX-2 protein that has, at a minimum, the functional activity of inhibiting an MLR. In the absence of a recited function, "fragment thereof" reads on any linear portion of an OX-2 protein, including single amino acids. The skilled artisan recognized that it would be highly unpredictable that fragments other than the extracellular domain would function in the instant methods unless the fragment also possessed at least the ability to inhibit an MLR.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. Since it is unpredictable as to which "fragments" of an OX-2 protein other than the extracellular domain would provide or maintain the enabling function of inhibiting an MLR; the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

*It is suggested that Applicant incorporate the functional limitations set forth above into any independent claim reciting a "fragment" of an OX-2 protein to obviate this rejection.*

12. It is noted that the CBA x DBA/2 resorption model is an art-recognized model of fetal loss (e.g., see Toder et al. Amer. J. Reprod. Immunol. 26:42-46 (1991); Tangri et al. Biol. Reprod. 49:850-856 (1993); Clark Amer. J. Reprod. Immunol. 32:290-293 (1994) and Gorczynski et al. Graft 4(5):338-345 (2001), IDS #14).

### 35 U.S.C. §§ 102 and 103

13. The following comments are noted regarding the teaching of Borriello et al. (J. Immunol. 158:4548-4554 May 15, 1997, IDS #5) and Borriello et al. (WO 97/21450, IDS):

In each reference, Borriello et al. observe that CHO cells transfected with OX-2 induced T cells to proliferate in the presence of anti-CD3 in an in vitro assay. Borriello et al. conclude that the function of OX-2 is to *stimulate* T cells.

However, the teachings of Borriello et al. are contradictory to the function observed for OX-2 in the instant disclosure. The instant application discloses that *agonists* of OX-2 actually *inhibit* an immune response *because OX-2 is a receptor that transmits a negative signal*.

That OX-2 transmit an inhibitory rather than stimulatory signal, as disclosed in the instant application, is also supported by the work of Hoek et al. (see e.g., US 2002/0192215).

Although Borriello et al. teach OX-2 and OX-2 fusion proteins comprising the extracellular domain fused to an immunoglobulin constant region sequence, and the application of agonists of OX-2 in various methods (e.g., pages 9-10 and 16-17); the teachings of Borriello et al. indicate that the methods employing agonists of OX-2 are for enhancing or stimulating an immune response.

Thus the teachings of Borriello et al. appear neither to anticipate claims drawn to methods of suppressing an immune response, nor render such methods obvious.

It is noted that rejections of record with respect to specific methods of inhibiting graft rejection in parent application USSN 09/570,367 were withdrawn essentially for the reasons set forth supra.

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*Conclusion*

14. No claim is allowed.

15. Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including the limitations of the base claim and any intervening claims.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark, whose telephone number is (703) 605-1209. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number for before Final submissions is (703) 872-9306.

Jessica Roark, Ph.D.  
Patent Examiner  
Technology Center 1600  
August 7, 2003

*Phillip Gambel*  
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*8/7/03*